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#43 Brief  
Reply (copies)

PATENT  
Customer No: 22,852  
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5/21/04

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of	)	
	)	
Marc ALIZON et al.	)	Group Art Unit: 1648
	)	
Serial No.: 08/466,921	)	Examiner: J. PARKIN
	)	
Filed: June 6, 1995	)	
	)	Confirmation No.: 3572
For: HIV-1 DNA FRAGMENTS	)	
THAT HYBRIDIZE TO GENOMIC	)	
HIV-1 DNA (As Amended)	)	
Commissioner for Patents		
P.O. Box 1450		
Alexandria, VA 22313-1450		

**SUPPLEMENTAL REPLY BRIEF**

In response to the Supplemental Examiner's Answer<sup>1</sup> dated March 12, 2004 (Paper No. 42), appellants submit the following remarks.

<sup>1</sup> Appellants note that the Board did not authorize a Supplemental Examiner's Answer under 37 C.F.R. § 1.193(b)(1). (Paper No. 41 at 5.) Nonetheless, appellants have filed this Supplemental Reply Brief to be responsive to the Supplemental Examiner's Answer and to respond to the Board's request for appellants' views regarding the effect of the decision in *Enzo Biochem., Inc. v. Gen-Probe, Inc.* on this Appeal.

1. **The Application Was Remanded By The Board In View Of *Enzo***

In an Order dated June 27, 2002, the Board remanded the application to the Examiner for consideration of the decision in *Enzo Biochem., Inc. v. Gen-Probe, Inc.*, 285 F.3d 1013, 62 U.S.P.Q.2d 1289 (Fed. Cir. 2002). (Paper No. 41<sup>2</sup>.) The Board indicated that it needed "an exchange of views between the examiner and appellants as to the effect, if any, the court's decision in Enzo Biochem has on the patentability of claims 62-73." (*Id.* at 4.) The Board also believed that "the Examiner should take a step back and review the patentability of allowed claims 39 through 52, 60, and 61 in light of the legal principles set forth in Eli Lilly and Enzo Biochem." (*Id.* at 4-5.)<sup>3</sup>

2. **The Decision In *Enzo* Was Vacated In *Enzo II***

As noted in the Supplemental Examiner's Answer dated March 12, 2004, the decision referred to by the Board was vacated in a subsequent decision, *Enzo Biochem., Inc. v. Gen-Probe, Inc.*, 296 F.3d 1316, 63 U.S.P.Q.2d 1609 (Fed. Cir. 2002). Thus, appellants will direct this Supplemental Reply Brief to appellants' views

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<sup>2</sup> In the Order, the Board indicated that appellants had erred in not discussing the *Univ of Cal. v. Eli Lilly* case. (Paper No. 41 at 3.) Appellants point out that this case was discussed on pages 18 and 19 of appellants' Brief in the context of appellants having an adequate description of claims 62-73.

<sup>3</sup> Since, in the Supplemental Examiner's Answer, the Examiner again found these claims fulfilled 35 U.S.C. § 112, appellants find no reason to address these allowed claims in this Reply.

on the effect of this decision ("*Enzo II*") on the rejection of appellants' claims under 35 U.S.C. § 112, first paragraph. Appellants will show that decision in *Enzo II* supports the patentability of claims 62-73.

**3. Deposits Of Nucleotide Sequences Can Fulfill The Written Description Requirement**

In *Enzo II*, the Court of Appeals for the Federal Circuit was faced with an issue of relevance to the claims on appeal in this application, namely, the compliance of genus claims to nucleic acids based on their hybridization properties with the written description requirement of 35 U.S.C. § 112, first paragraph. Enzo's claims were directed to nucleic acids that selectively hybridized to a particular species of bacteria. 296 F.3d at 1321-22, 63 U.S.P.Q.2d at 1611. Enzo had deposited three nucleic acid sequences meeting the limitations of the claims. 296 F.3d at 1325, 63 U.S.P.Q.2d at 1613. The court began its analysis by holding that "reference in the specification to deposits of nucleotide sequences describe those sequences sufficiently to the public for purposes of meeting the written description requirement." 296 F.3d at 1326, 63 U.S.P.Q.2d at 1614.

**4. Appellants' Deposit Fulfills The Written Description Requirement Of 35 U.S.C. § 112, First Paragraph, For Appellants' Full-Length Clone Of HIV-1**

Appellants' claims 63, 65, 67, 69, 71, and 73 recite a deposited full-length clone of HIV-1 that was described in the

specification as "λJ19." In view of the above holding in *Enzo II*, appellants' reference in the specification to this deposit describes the sequence of this full-length clone of HIV-1 sufficiently to the public for purposes of meeting the written description requirement.

**5. Fragments Or Mutants Of Deposited Sequences That Hybridize To Deposited DNAs May Be Fully Described Based On Information Obtainable From The Deposits**

In *Enzo II*, the court addressed the issue whether Enzo had adequately described fragments or mutants of deposited sequences that hybridized to the deposited DNAs. The court indicated that the claims might be adequately described, but remanded the case since this was an issue of fact, stating:

On the other hand, because the deposited sequences are described by virtue of a reference to their having been deposited, it may well be that various subsequences, mutations, and mixtures of those sequences are also described to one of skill in the art. We regard that question as an issue of fact that is best resolved on remand. Because the district court's grant of summary judgment was based on its conclusion that Enzo's deposits could not satisfy the written description requirement as a matter of law, we reverse the district court's grant of summary judgment that claims 4 and 6 are invalid for failure to meet the written description requirement. On remand, the court should determine whether a person of skill in the art would glean from the written description, including information obtainable from the deposits of the claimed sequences, subsequences, mutated variants, and mixtures sufficient to demonstrate possession of the generic scope of the claims.

296 F.3d at 1326-27, 63 U.S.P.Q.2d at 1615. Thus, claims to fragments or mutants of deposited sequences that hybridize to

the deposited DNAs may be sufficiently described because of information obtainable from the deposits.

6. **Enzo II Provides Guidance On Determining Whether Genus Claims To Nucleic Acids Based On Their Hybridization Properties Fulfill The Written Description Requirement**

In *Enzo II*, the court provided guidance as to how to determine whether genus claims to nucleic acids based on their hybridization properties fulfill the written description requirement of 35 U.S.C. § 112, first paragraph:

The PTO has also provided a contrasting example of genus claims to nucleic acids based on their hybridization properties, and has determined that such claims may be adequately described if they hybridize under highly stringent conditions to known sequences because such conditions dictate that all species within the genus will be structurally similar. See *id.*, Example 9, at 35-37. Whether the disclosure provided by the three deposits in this case, coupled with the skill of the art, describes the genera of claims 1-3 and 5 is a fact question the district court did not address. On remand, the district court should determine, consistently with the precedent of this court and the PTO's Guidelines, whether one skilled in the art would consider the subject matter of claims 1-3 and 5 to be adequately described, recognizing the significance of the deposits and the scope of the claims.

296 F.3d at 1327-28, 63 U.S.P.Q.2d at 1615.

Thus, in *Enzo II*, the Federal Circuit cited with approval the PTO's Guidelines with respect to compliance of genus claims to nucleic acids, based on their hybridization properties, with the written description requirement of 35 U.S.C. § 112, first paragraph. That is, the court acknowledged that this type of claim may be adequately described because the hybridization

conditions may dictate that all species within the genus will be structurally similar.

**7. Appellants' Claims Are Adequately Described  
Because All Species Within The Claimed  
Genus Will Be Structurally Similar**

Application of the analysis set forth in *Enzo II* demonstrates that appellants' claims are adequately described because the recitations in appellants' claims dictate that all species within the claimed genus will be structurally similar. Appellants' claims 62-73 recite an "HIV-1" DNA fragment. Since, by definition, all HIV-1 viruses are structurally related, each DNA fragment of HIV-1 must maintain this structural relationship. Thus, the recitation in these claims that this DNA fragment is an "HIV-1" DNA fragment imposes a structural limitation on the identity of the DNA fragment.

In addition, similar to language in the claims at issue in *Enzo II*, the DNA fragments of claims 62-73 hybridize to the genomic DNA of HIV-1 under specific hybridization conditions. The recited conditions impose an additional structural limitation on the identity of the HIV-1 DNA fragment, namely, it must have a sufficient quantity of nucleotides of HIV-1 to hybridize to HIV-1 genomic DNA under the recited selective hybridization conditions.

Consequently, the recitations in claims 62-73 impose two structural limitations on the claimed DNA fragment: 1) it must

be an HIV-1 DNA fragment and 2) it must have a sufficient quantity of nucleotides of HIV-1 to hybridize to HIV-1 genomic DNA under the recited conditions. These recitations in the claims impose structural limitations on the claimed DNA fragment, and dictate that all species within the genus of appellants' claimed DNA fragments will be structurally similar to the genomic DNA of HIV-1. Thus, according to the test set forth in *Enzo II*, appellants' claims 62-73 fulfill the requirements of 35 U.S.C § 112, first paragraph.

**8. Claims 63, 65, 67, 69, 71, and 73 Are Adequately Described Because All Species Within The Claimed Genus Will Be Structurally Similar to the Deposited Isolate**

In addition, appellants' claims 63, 65, 67, 69, 71, and 73 recite that the hybridizing DNA is "λJ19." As discussed *supra*, appellants' reference in the specification to this clone describes the sequence of this full-length clone of HIV-1 sufficiently to the public for purposes of meeting the written description requirement. See *Enzo II*, 296 F.3d at 1326, 63 U.S.P.Q.2d at 1614. Thus, claims 63, 65, 67, 69, 71, and 73 further restrict the structural identity of the claimed genus. That is, all species within the genus of DNA fragments recited in these claims will be structurally similar to λJ19 DNA, the sequence of which is fully described by reference to its deposit in the specification. Thus, for this additional reason, claims

63, 65, 67, 69, 71, and 73 fulfill the requirements of 35 U.S.C § 112, first paragraph.

**9. The Discussion Of The "Possession" Test In *Enzo II* Does Not Alter The Fact That Appellants' Claims Are Fully Described**

With respect to the effect of the discussion of the "possession" test in *Enzo II* on appellants' position on Appeal, the court's discussion does not diminish the strength of appellants' arguments in any way. In *Enzo II*, the court found that a showing of possession alone does not cure a lack of a written description in the specification. 296 F.3d at 1330, 63 U.S.P.Q.2d at 1617. In the Brief, appellants did not argue that they had possession, but were lacking a written description. Rather, appellants argued that they had possession of the invention based on descriptions found in the specification. That is, appellants argued that the written description found in the specification showed possession of the invention. Thus, the discussion of the "possession" test in *Enzo II* is inapplicable to appellants' position on Appeal.

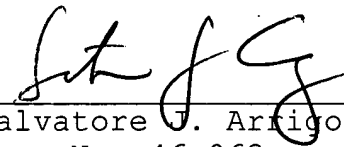


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Respectfully submitted,

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